In the Drawing:

The attached drawing sheet includes formalized drawings of FIGs. 1-3. These sheets which include FIGs. 1-3 replace the original sheet including FIGs. 1-3.

Attachment: One (1) Replacement Drawing Sheet.

REMARKS

I. Status of the Claims:

Claims 1-37 are currently pending. Claims 1-14, 22-33 and 35 have been withdrawn from consideration. The Applicants continue to traverse the Restriction/Election Requirement.

By this Amendment, claims 15, 17-19, 21, 23, 34 and 37 have been amended. No new matter has been introduced. Entry of this Supplemental Preliminary Amendment prior to examination on the merits is respectfully requested.

Upon entry of this Amendment, claims 1-37 would be pending.

II. Sequence Compliance Rules:

The Examiner has objected to the specification as failing to comply with the requirements of 37 C.F.R. § 1.821(d) because the sequences on page 13 are not followed by a sequence identifier.

In accordance with the Examiner's suggestions, the specification has been amended to incorporate the sequence identifiers for the two sequences on page 13. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Objection to the Drawings:

The drawings are objected to because they contain multiple figures on a single sheet. The Applicant submits herewith formal drawings, in which each Figure on the sheet is separately labeled, e.g., FIG. 1, FIG.2 and FIG.3, and comply with the

requirements set forth in 37 C.F.R. §1.121. Approval and entry of these drawings are respectfully requested.

IV. Objection to the Specification:

The specification is objected to because of some informalities as to the use of trademarks. The specification has been amended in accordance with the Examiner's suggestions to capitalize and identify trademarks. Thus, reconsideration and withdrawal of the objection to the specification are respectfully requested.

V. Rejection Under 35 U.S.C. § 112:

Claims 15-21, 34 and 36-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

The claims have been amended to address most of the Examiner's concerns identified in the Office Action.

Regarding the language "substantially linear" in claims 15 and 37, the Applicants respectfully submit that term "substantially" as applied in these claims is definite. Section 2173.05 (b) of the MPEP states:

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

The Examiner has not set forth any objective and supported rationale as to why one of ordinary skill in the art would not understand what is claimed in light of the specification, or explained how the current claims are similar to the facts in Ex parte Brummer, 12 USPQ2d 1653 (Bd. Pat. App. & Inter. 1989). See MPEP §2173.05(b). Indeed, the term "substantially" has been found to be definite in a number of cases. Id. The Applicants respectfully submit that one of ordinary skill in the art would understand what is claimed in claims 15 and 37 in view of the specification.

VI. Rejection Under 35 U.S.C. §§ 102 and 103:

Claims 15-18, 34 and 36-37 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ward et al. (US 2003/0044826) with a priority date of August 21, 2001. Claims 19-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ward et al. as applied to claims 15-18 and 36-37, and further in view of Peirson et al. (Nucleic Acids Research, Vol. 31, pages 1-7, July 2003).

Claim 15 is directed to a system that includes a memory for storing a signal representative of the amount of reaction product for each of the cycles, a processing unit for calculating a logarithm of the signal, a memory for storing the logarithm, and a reaction efficiency calculator, for calculating reaction efficiency from a dependence of the signal on the cycle number. The system further includes a selector adapted to select a set of cycles over which the dependence of the logarithm on the cycle number is substantially linear, and wherein the efficiency calculator includes an estimator for estimating a slope of the dependence of the logarithm of the signal on the cycle number for the selected set of cycles.

On the contrary, although Ward uses linear regression of the logarithm of a PCR fluorescence signal, it uses the linear regression to identify an exponential threshold. See e.g., Ward, Figs. 3 and 5 (step 360). The threshold is then used to identify a threshold cycle to construct *standard curves* in order to compute initial target concentration. See e.g., Ward, Figs. 3 (step 370). Although paragraph 67 as identified by the Examiner does refer to assessing the relative efficiency of the amplification reaction, this is disclosed to be done by using the *standard curve* derived. The formula in paragraph 85 cited by the Examiner relates the threshold cycle to the reaction efficiency. It is used to calculate the initial amount of target from the *standard curve* (see paragraph 86). There is thus no disclosure or suggestion in Ward of an efficiency calculator which calculates reaction efficiency from a dependence of the fluorescence signal on the cycle number, let alone a disclosure or suggestion of the efficiency calculator including an estimator for estimating the slope of the dependence of the logarithm on the cycle number.

Further, Ward is closer to the prior art described in the introduction of the present application (e.g., page 2, line 15 to page 3, line 26) in that it defines a threshold which is then used for constructing standard curves. Although Ward uses linear regression to find the threshold, it is otherwise entirely conventional in the use of standard curves. Although Ward uses linear regression, it does not go beyond a mere ancillary use to define the threshold which is then used for construction of a standard curve. This clearly illustrates that before the date of invention, one of ordinary skill in the art would have considered that the *standard curve* was the only way to determine reaction efficiency. In the present claimed arrangement, there is no need for calculating

standard curves, instead reaction efficiency is estimated directly from the dependence of the logarithm of a signal representative of the amount of reaction product.

In view of the foregoing, claim 15 and its dependent claims are distinguishable over the cited reference.

CONCLUSION

Based on the foregoing remarks, the Applicant respectfully requests reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this Preliminary Amendment, or credit any overpayment, to Deposit Account No. 13-4500, Order No. 4586-4001.

Respectfully submitted,
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